Appointment

From: Birchfield, Norman [Birchfield.Norman@epa.gov]

Sent: 10/25/2016 1:58:17 PM

To: Birchfield, Norman [Birchfield.Norman@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Glenn, Barbara

[Glenn.Barbara@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Jinot, Jennifer [Jinot.Jennifer@epa.gov]; Cogliano, Vincent [cogliano.vincent@epa.gov]; Vandenberg, John [Vandenberg.John@epa.gov]; Jones, Samantha

[Jones.Samantha@epa.gov]; Bateson, Thomas [Bateson.Thomas@epa.gov]; thayer@niehs.nih.gov

CC: Ross, Mary [Ross.Mary@epa.gov]

Subject: Formaldehyde LHP discussion **Location**: DCRoomPYS11731-Capital

Start: 1/10/2017 3:00:00 PM **End**: 1/10/2017 4:30:00 PM

Show Time As: Busy

Required Bussard, David; Glenn, Barbara; Kraft, Andrew; Jinot, Jennifer; Cogliano, Vincent; Vandenberg, John; Jones,

Attendees: Samantha; Bateson, Thomas; thayer@niehs.nih.gov

Optional Ross, Mary

Attendees:

Call in: Ex. 6 Personal Privacy (PP)

Proposed Agenda

10:00-10:10: background on topic and focus for discussion (Barbara and Andrew)

10:10-10:20: restate/ reword concerns raised during ERC review (Vince)

10:20-10:35- lay out current IUR approach and how ERC concerns addressed in draft (Jennifer)

10:35-11:20: discussion (all)

11:20-11:25: summarize decisions and next steps on this issue (David/Samantha)

11:25-11:30: identify any other related issues needing to be addressed (David/Samantha)

NAS Recommendation (LHP Hazard Decisions):

"EPA evaluated the evidence of a causal relationship between formaldehyde exposure and several groupings of LHP cancers— "all LHP cancers," "all leukemias," and "myeloid leukemias." The committee does not support the grouping of "all LHP cancers" because it combines many diverse cancers that are not closely related in etiology and cells of origin. The committee recommends that EPA focus on the most specific diagnoses available in the epidemiologic data, such as acute myeloblastic leukemia, chronic lymphocytic leukemia, and specific lymphomas."

In the current draft:

Ex. 5 Deliberative Process (DP)

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NAS Recommendation (unit risk):

"Regarding calculation of unit risks, the committee agrees that the NCI studies and the findings of the two follow-ups are a reasonable choice because they are the only ones with sufficient exposure and dose-response data for risk estimation. However, the studies are not without their weaknesses, and these need to be clearly articulated in the revised IRIS assessment... The committee agrees that EPA's choice of NPC, Hodgkin lymphoma, and leukemia data from the NCI studies to estimate a unit risk is appropriate given that the analysis of Hodgkin lymphoma and leukemia primarily supports the assessment of uncertainty and the magnitude of potential cancer risk. However, the mode of action for formaldehyde-induced Hodgkin lymphoma and leukemia has not been clearly established. Moreover, the highly limited systemic delivery of formaldehyde draws into question the biologic feasibility of causality between formaldehyde exposure and the two cancers. Thus, substantial uncertainties in using Hodgkin lymphoma and leukemia for consensus cancer risk estimation remain."

In the current draft:

Ex. 5 Deliberative Process (DP)

FOCUS FOR TODAY'S DISCUSSION:

Ex. 5 Deliberative Process (DP)